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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,242	09/12/2000	Timothy Myers	41118	6165

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EXAMINER
ZHOU, SHUBO

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/02/2002 7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/660,242	Applicant(s) MYERS ET AL.	
	Examiner Shubo "Joe" Zhou	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1. Claims 1-10, drawn to method of determining a disease state of a subject using protein markers, classified in Class 435, subclass 7.1.

2. Claims 11-12, and 17-18, drawn to protein markers, classified in Class 530, subclass 300 or 350.

3. Claims 13-14, and 19-20, drawn to binding reagents bound to a label specific for protein markers. The class and subclass of this group is currently un-assignable because the chemical nature, etc. of the binding reagents is unknown.

4. Claims 15-16, and 32, drawn to method of monitoring efficacy of a therapy for a disease state, classified in Class 435, subclass 7.1.

5. Claims 21, 26, and 34, drawn to method of screening candidate compounds biological activity against diseases, classified in Class 436, subclass 500. If this group is elected, then the below Species Election requirement also is required.

6. Claims 22-23, and 33, drawn to pharmaceutical compositions comprising a modifier of the activity of a protein marker. The class and subclass of this group is currently un-assignable because the chemical nature, etc. of the modifier is unknown.

7. Claims 24 and 25, drawn to methods of treating a disease with a modifier of the activity of a protein marker. The class and subclass of this group is currently un-assignable because the chemical nature, etc. of the modifier is unknown.

8. Claims 27-28, drawn to method of identifying biological pathways involving a disease, classified in Class 702, subclass 19. If this group is elected, then the below Species Election requirement also is required.

9. Claims 29-31, drawn two dimensional distribution of proteins. The class and subclass of this group is currently un-assignable because the claimed subject matter is unclear. If the "distribution" of proteins is claimed, it is not a patentable subject matter.

10. Claims 35-36, drawn to method of determining whether a combination of proteins together from a protein marker of a disease state, classified in Class 702, subclass 19. If this group is elected, then the below Species Election requirement also is required.

11. Claim 37, drawn to composition comprising the combination of protein markers, classified in Class 514, subclass 2-21.

12. Claim 38, drawn to binding reagents bound to protein markers. These binding reagents are unrelated to those in Group 3. The class and subclass of this group is currently un-assignable because the chemical nature, etc. of the binding reagents is unknown.

13. Claim 39, drawn to method of finding drug development targets for diseases, classified in Class 514, subclass 2-21.

14. Claims 40 and 43-44, drawn to a drug development target for diseases, classified in Class 514, subclass 2-21.

15. Claims 41-42, drawn to a binding agent to a drug development target for diseases. The class and subclass of this group is currently un-assignable because the chemical nature, etc. of the binding reagents is unknown.

16. Claim 45, drawn to method of finding a submarker for diseases, classified in Class 514, subclass 2-21.

17. Claim 46, drawn to a protein submarker for diseases, classified in Class 435, subclass 7.1.

18. Claim 47, drawn to a binding agent to a protein submarker. The class and subclass of this group is currently un-assignable because the chemical nature, etc. of the binding reagents is unknown.

19. Claim 48, drawn to method of finding an index marker for diseases, classified in Class 514, subclass 2-21.

20. Claim 49, drawn to an index marker, classified in Class 435, subclass 7.1.

21. Claim 50, drawn to a method of cloning a gene encoding a protein marker, classified in Class 435, subclass 91.1.

22. Claims 51-52, drawn to a gene encoding a protein marker, classified in Class 536, subclass 23.1.

23. Claims 53 and 55, drawn to a method of determining whether plural agents act in an additive manner, classified in Class 435, subclass 7.1.

24. Claim 54, drawn to a pharmaceutical composition comprising unknown agents. The class and subclass of this group is currently un-assignable because the chemical nature, etc. of the binding reagents is unknown.

The inventions are distinct, each from the other because of the following reasons:

The sets of inventions (1-2, 4-5, and 8), 3, (6 and7), 9, 10, 11, 12, (13-14), 15, (16-17), 18, (19-20), (21-22), and (23-24) are independent with respective to each other because the methods as claimed are distinct both physically and functionally, require

different process steps, reagents and parameters, and produce different products. The products as claimed, i.e. the protein markers, the index markers, the binding agents, etc. are distinct both physically and functionally also, and require different process steps, reagents and parameters to produce. Consequently, these inventions have acquired a separate status in the art as a separate subject for inventive effect and are usually published separately. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Thus, examination of the invention groups together would impose an undue search burden to the Office.

The inventions of Groups 2 and (1, 4-5, and 8) are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the protein markers of Group 2 can be used in the distinct processes of the inventions of Groups (1, 4-5, and 8), which are directed to processes of determining a disease state of a subject using protein markers, monitoring efficacy of a therapy for a disease state, screening candidate compounds biological activity against diseases, and identifying biological pathways involving a disease, respectively. These processes are clearly distinct because they involve different steps and require distinct reagents.

The inventions of Groups 6 and 7 are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the modifier composition of Group 6 can be used in the process of Group 7, which is

directed to method of treating a disease. Alternatively, the composition can be used for detecting binding agents to the modifiers, which is clearly a distinct usage of the modifier composition.

The inventions of Groups 13 and 14 are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different product or (2) the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case, the drug development targets of Group 14 can be produced by the process of invention of Group 13 by testing protein markers in a biological samples. Alternatively, since the sequences of the protein markers are known or can be known by chemical sequencing, the protein markers can be made by in vitro chemical synthesis, which is clearly a distinct way of making.

The inventions of Groups 16 and 17 are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different product or (2) the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case, the protein submarker of Group 17 can be produced by the process of invention of Group 16 by comparing protein markers with submarkers in terms of their changes in diseases. Alternatively, since the sequences of the protein submarkers are known or can be known by chemical sequencing, the protein submarkers can be made by in vitro chemical synthesis, which is clearly a distinct way of making.

The inventions of Groups 19 and 20 are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially

different product or (2) the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case, the index markers of Group 20 can be produced by the process of invention of Group 19 involving a particular physiological state. Alternatively, since the sequences of the index markers are known or can be known by chemical sequencing, the index markers can be made by in vitro chemical synthesis, which is clearly a distinct way of making.

The inventions of Groups 21 and 22 are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different product or (2) the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case, the genes of Group 22 can be produced by the process of invention of Group 21 involving recombination. Alternatively, since the sequences of the genes are known or can be known by chemical sequencing, the genes can be made by in vitro chemical synthesis, which is clearly a distinct way of making.

The inventions of Groups 23 and 24 are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different product or (2) the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case, the agents in the composition of Group 24 can be produced by the process of invention of Group 23 involving exposing subject to agents. Alternatively, since the agents are protein markers and the sequences of the agents are known or can be known by chemical sequencing, the agents can be made by in vitro chemical synthesis, which is clearly a distinct way of making.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.
Patent Examiner

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER